IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| OSI PHARMACEUTICALS, LLC, PFIZER INC., and GENENTECH, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| BRECKENRIDGE PHARMACEUTICAL, INC. and NATCO PHARMA LTD., | ) | |
| Defendants. | ) | |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs OSI Pharmaceuticals, LLC ("OSI"), Pfizer Inc. ("Pfizer") and Genentech, Inc. ("Genentech") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Breckenridge Pharmaceutical Inc., ("Breckenridge"), and Natco Pharma Ltd. ("Natco") (collectively, "Breckenridge/Natco") for patent infringement and allege as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, the Federal Food, Drug, and Cosmetic Act, Title 21 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 et seq., arising from Breckenridge/Natco's filing of an Abbreviated New Drug Application No. 208488 ("Breckenridge/Natco ANDA" or "ANDA No. 208488") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of TARCEVA® ("Breckenridge/Natco's Proposed Generic Products") prior to the expiration of certain patents that relate to that product, United States Reissued Patent No. RE 41,065 ("the RE '065 patent"), and United States Patent No. 6,900,221 ("the '221 patent").

## THE PARTIES

2. Plaintiff OSI is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 1 Astellas Way, Northbrook, IL 60062.

3. Plaintiff Pfizer is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located at 235 East 42nd Street, New York, New York 10017.

4. Plaintiff Genentech is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 1 DNA Way, South San Francisco, California 94080-4990.

5. On information and belief, Defendant Breckenridge is a corporation existing under the laws of the State of Florida, with its principal place of business at 6111 Broken Sound Parkway NW, Suite 170, Boca Raton, Fl. 33487.

6. On information and belief, Defendant Natco is an Indian company having a principal place of business at Natco House; Road No. 2, Banjara Hills, Hyderabad-50003, India.

7. On information and belief, Natco worked in active concert and participation with Breckenridge to manufacture Breckenridge/Natco's Proposed Generic Products and to prepare the Breckenridge/Natco ANDA

8. On information and belief, Natco has partnered with Breckenridge to market and distribute Breckenridge/Natco's Proposed Generic Products complained of herein, including in this District.

## JURISDICTION AND VENUE

9. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Breckenridge, *inter alia*, because: (a) Breckenridge has purposefully directed its activities at residents and corporate entities within the State of Delaware; (b) the claims set forth herein arise out of or relate to those activities; (c) Breckenridge has availed itself of the rights and benefits of Delaware; (d) Breckenridge's contacts with the State of Delaware (direct and/or indirect) are continuous and systematic; and (e) it is reasonable and fair for this Court to exercise personal jurisdiction over Breckenridge.

11. On information and belief, Breckenridge markets and sells pharmaceutical products throughout the United States, including the State of Delaware, and Breckenridge derives substantial revenue from Delaware drug sales.

12. On information and belief, Breckenridge's sales and commercial activities have "nationwide" reach, as it has stated: "Breckenridge has an experienced sales team that reaches all classes of trade including: Retail Pharmacy Chains, Mail Order Pharmacies, Pharmacy Benefit Managers and Group Purchasing Organizations as well as Wholesalers and Distributors nationwide." *See* http://www.bpirx.com/html/index.aspx?p32sda=salesandmarketing&psdge87d=296&tl97abi=16 (last visited November 10, 2015).

13. On information and belief, Breckenridge directly or through its affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by

innovator pharmaceutical companies, throughout the United States, including in the State of Delaware.

14. On information and belief, Breckenridge has affiliations with the State of Delaware that are pervasive, continuous, and systematic. On information and belief, Breckenridge engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware and to the residents of the State of Delaware.

15. On information and belief, Breckenridge regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from services or things used or consumed in the State of Delaware.

16. This Court also has personal jurisdiction over Breckenridge because, among other things, Breckenridge has been a litigant and consented to jurisdiction in the State of Delaware in one or more prior cases as a (a) plaintiff alleging causes of action, including patent infringement (*e.g., Pamlab L.L.C., and Breckenridge Pharmaceutical, Inc., v. Acella Pharma., LLC,* C.A. No. 12-1403-SLR (D. Del.)); (b) defendant (*e.g., Bayer Intellectual Property GmbH et al v. Aurobindo Pharma Limited et al*., C.A. No.15-902 (D. Del)); and (c) counterclaim plaintiff (*e.g., Par Pharm., Inc., et al. v. Breckenridge Pharm., Inc.*, C.A. No. 13-1114-SLR-SRF (D. Del.)).

17. Breckenridge is also subject to personal jurisdiction in the State of Delaware because, among other things, Breckenridge has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs that are organized and existing under the laws of the State of Delaware, and which manufacture, market and/or sell TARCEVA® for use throughout the United States, including the State of Delaware. On

information and belief, Breckenridge intends to engage in the commercial manufacture, use, and/or sale of Breckenridge/Natco's Proposed Generic Products before the expiration of the RE '065 and '221 patents throughout the United States, including in the State of Delaware.

18. On information and belief, upon approval of the Breckenridge/Natco ANDA, Breckenridge and/or its affiliates or agents will market, sell and/or distribute Breckenridge/Natco's Proposed Generic Products throughout the United States, including in the State of Delaware, and will derive substantial revenue therefrom.

19. On information and belief, upon approval of the Breckenridge/Natco ANDA, Breckenridge and/or its affiliates or agents will place Breckenridge/Natco's Proposed Generic Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in the State of Delaware.

20. On information and belief, this Court has personal jurisdiction over Natco because Natco has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed itself of this forum, including through its wholly owned subsidiary Natco Pharma Inc., a Delaware company, by among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Natco pharmaceutical products in the State of Delaware, and deriving substantial revenue from such activities.

21. On information and belief, this Court also has personal jurisdiction in the State of Delaware over Natco because, among other things, Natco has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to

Plaintiffs that are organized and existing under the laws of the State of Delaware, and which manufacture, market and/or sell TARCEVA® for use throughout the United States, including the State of Delaware. The Breckenridge/Natco ANDA evidence Natco's intent to engage in the commercial manufacture, use, and/or sale of Breckenridge/Natco's Proposed Generic Products before the expiration of the RE '065 and '221 patents throughout the United States, including in the State of Delaware, which will lead to foreseeable harm and injury to Plaintiffs that are organized and existing under the laws of the State of Delaware.

22. On information and belief, Natco's subsidiary Natco Pharma Inc. has registered to do business in Delaware and has appointed a registered agent in Delaware for the receipt of service of process.

23. On information and belief, Natco directly or through its affiliates and agents and/or in concert with Breckenridge develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in the State of Delaware. *See, e.g.*, http://www.indiainfoline.com/article/news-top-story/natco-launches-anastrazole-in-us-113101301460_1.html (last visited November 13, 2015) ("NATCO Pharma Ltd announce the launch, in the United States of America, of the generic version of Anastrazole 1 mg tablets, consequent to the final approval received from the US FDA. The product has been launched through the Company's marketing partners.").

24. On information and belief, Natco has partnered with Breckenridge to market and distribute various proposed generic drugs, and is currently partnering with Breckenridge to market and distribute Breckenridge/Natco's Proposed Generic Product throughout the United States, including in the State of Delaware. *See* http://www.firstwordpharma.com

/node/1233623#axzz3rO3FeuKT; http://articles.economictimes.indiatimes.com/2014-10-21/news/55279578_1_natco-pharma-nuvigil-us-health-regulator; http://www.prnewswire.com/news-releases/breckenridge-pharmaceutical-inc-announces-paragraph-iv-anda-litigation-with-sanofi-for-its-anda-cabazitaxel-solution-iv-infusion-jevtana-300034726.html (last visited November 13, 2015).

25. On information and belief, Natco has filed with the FDA a Drug Master File for Erlotinib. *See* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm (last visited November 13, 2015).

26. On information and belief, this Court also has personal jurisdiction over Natco because Natco has been sued in the State of Delaware, and has been a counterclaim plaintiff in this State and did not challenge this Court's exercise of personal jurisdiction over it. *See Cephalon, Inc. v. Breckenridge Pharm. Inc. et al.*, C.A. No. 14-0671-GMS (D. Del); *Cephalon, Inc. et al. v. Breckenridge Pharm., Inc., and Natco Pharma Ltd.*, C.A. No. 11-1070-GMS (D. Del.).

27. On information and belief, the filing of the Breckenridge/Natco ANDA No. 208488 evidences Breckenridge/Natco's intent to compete with Plaintiffs and place Breckenridge/Natco's Proposed Generic Product into the State of Delaware where Plaintiffs' TARCEVA® drug product is currently sold.

28. In the alternative, this Court also has personal jurisdiction over Natco pursuant to Fed. R. Civ. P. 4(k)(2).

29. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

## THE PATENTS-IN-SUIT

30. On May 5, 1998, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued U.S. Patent No. 5,747,498 ("the '498 patent"), entitled "Alkynyl and Azido-Substituted 4-Anilinoquinazolines" to inventors Rodney Caughren Schnur and Lee Daniel Arnold.

31. On February 27, 2008, OSI and Pfizer filed with the USPTO an application, Serial No. 12/038,530, for reissue of the '498 patent. On December 29, 2009, the USPTO duly and lawfully reissued the '498 patent as the RE '065 patent, entitled "Alkynyl and Azido-Substituted 4-Anilinoquinazolines" to inventors Rodney Caughren Schnur and Lee Daniel Arnold. A copy of the RE '065 patent is attached hereto as Exhibit A.

32. OSI and Pfizer are owners of the RE '065 patent and Genentech is a co-exclusive licensee of the RE '065 patent.

33. On May 31, 2005, the USPTO duly and lawfully issued the '221 patent, entitled "Stable Polymorph on N-(3-Ethynylphenyl)-6, 7-Bis(2MethoxyEthoxy)-4-Quinazolinamine Hydrochloride, Methods of Production, and Pharmaceutical Uses Thereof" to inventors Timothy Norris, Jeffrey W. Raggon, Richard D. Connell, James D. Moyer, Michael J. Morin, Shama M. Kajiji, Barbara A. Foster, Karen J. Ferrante, and Sandra L. Silberman. A copy of the '221 patent is attached hereto as Exhibit B.

34. OSI is the owner of the '221 patent and Genentech is a co-exclusive licensee of the '221 patent.

## THE TARCEVA® DRUG PRODUCT

35. OSI holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for erlotinib hydrochloride tablets (NDA No. 021743), which OSI and Genentech market and sell under the

trade name TARCEVA®. The claims of the RE '065 and '221 patents cover, *inter alia*, TARCEVA® and its methods of use.

36. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the RE '065, and '221 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to TARCEVA®.

**ACTS GIVING RISE TO THIS SUIT**

37. Pursuant to Section 505 of the FFDCA, Breckenridge/Natco filed an ANDA for erlotinib hydrochloride tablets, seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of erlotinib hydrochloride tablets 25 mg, 100 mg and 150 mg ("Breckenridge/Natco's Proposed Generic Products"), before the patents in suit expire. The Breckenridge/Natco ANDA number is 208488.

38. On information and belief, in connection with the filing of the Breckenridge/Natco ANDA as described in the preceding paragraph, Breckenridge/Natco has provided written certifications to the FDA, as called for by Section 505 of the FFDCA, which allege that the claims of the RE '065 and '221 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Breckenridge/Natco's Proposed Generic Products.

39. No earlier than October 5, 2015, Breckenridge sent written notice of the ANDA No. 208488 filing to OSI, which received such notice no earlier than October 6, 2015. The notice letter referred to ANDA No. 208488 as being from Breckenridge and Breckenridge's ANDA. The notice alleged that the RE '065 and '221 patents are invalid, unenforceable, and/or will not be infringed by Breckenridge. Breckenridge's notice also informed OSI that Breckenridge seeks approval to market Erlotinib hydrochloride tablets 25 mg, 100 mg and 150 mg before the patents

in suit expire. On information and belief, Breckenridge has acted in concert with Natco in the preparation and filing of ANDA No. 208488.

40. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of Plaintiffs' receipt of Breckenridge's notice.

**COUNT I**
**Breckenridge/Natco's filing of the ANDA infringed the RE '065 Patent**

41. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-40.

42. Breckenridge/Natco's submission of ANDA No. 208488 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Breckenridge/Natco's Proposed Generic Products, prior to the expiration of the 'RE '065 patent, constituted infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

43. Unless enjoined by this Court, Breckenridge/Natco, upon FDA approval of Breckenridge/Natco's ANDA, will infringe the RE '065 patent by making, using, offering to sell, importing, and selling Breckenridge/Natco's Proposed Generic Products in the United States, and by actively inducing and contributing to infringement by others.

44. On information and belief, Breckenridge/Natco, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the RE '065 patent.

45. On information and belief, Breckenridge/Natco plans and intends to, and will, actively induce infringement of the RE '065 patent when ANDA No. 208488 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

46. On information and belief, Breckenridge/Natco knows that Breckenridge/Natco's Proposed Generic Product is especially made or adapted for use in infringing the RE '065 patent and that Breckenridge/Natco's Proposed Generic Product is not suitable for any substantial noninfringing uses.

47. On information and belief, under 35 U.S.C. § 271(c), Breckenridge/Natco plans and intends to, and will, contribute to the infringement of the RE '065 patent immediately and imminently upon approval of ANDA No. 208488.

48. The foregoing actions by Breckenridge/Natco constitute and/or would constitute infringement of the RE '065 patent, active inducement of infringement of the RE '065 patent and/or contribution to the infringement by others of the RE '065 patent.

49. On information and belief, Breckenridge/Natco acted without a reasonable basis for believing that it would not be liable for infringing the RE '065 patent, actively inducing infringement of the RE '065 patent and/or contributing to the infringement by others of the '065 patent.

50. There is a justiciable controversy between the parties hereto as to infringement of the RE '065 patent.

51. Plaintiffs will be substantially and irreparably damaged and harmed if Breckenridge/Natco's infringement of the RE '065 patent is not enjoined.

52. Plaintiffs do not have an adequate remedy at law.

53. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT II**

**Declaratory Judgment of Infringement of the RE '065 Patent by Breckenridge/Natco**

54. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-53.

55. On information and belief, Breckenridge/Natco's Proposed Generic Product contains the compound Erlotinib recited in one or more claims of the RE '065 patent.

56. On information and belief, Breckenridge/Natco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Breckenridge/Natco's Proposed Generic Product soon after FDA approval of ANDA No. 208488.

57. Such conduct will constitute direct infringement of one or more claims on the RE '065 patent under 35 U.S.C. § 271(a), inducement of infringement of the RE '065 patent under 35 U.S.C. § 271(b), and contributory infringement of the RE '065 patent under 35 U.S.C. § 271(c).

58. Breckenridge/Natco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 208488.

59. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Breckenridge/Natco as to liability for the infringement of the RE '065 patent. Breckenridge/Natco's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Breckenridge/Natco's threatened imminent actions.

60. Plaintiffs will be irreparably harmed if Breckenridge/Natco is not enjoined from infringing the RE '065 patent.

61. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT III**
**Breckenridge/Natco's filing of the ANDA infringed the '221 patent**

62. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-61.

63. Breckenridge/Natco's submission of ANDA No. 208488 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Breckenridge/Natco's Proposed Generic Products, prior to the expiration of the '221 patent, constituted infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

64. Unless enjoined by this Court, upon FDA approval of Breckenridge/Natco's ANDA, Breckenridge will infringe the '221 patent by making, using, offering to sell, importing, and selling Breckenridge/Natco's Proposed Generic Products in the United States, and by actively inducing and contributing to infringement by others.

65. On information and belief, Breckenridge/Natco, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '221 patent.

66. On information and belief, Breckenridge/Natco plans and intends to, and will, actively induce infringement of the '221 patent when ANDA No. 208488 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

67. On information and belief, Breckenridge/Natco knows that Breckenridge/Natco's Proposed Generic Product is especially made or adapted for use in infringing the '221 patent and that Breckenridge/Natco's Proposed Generic Product is not suitable for any substantial noninfringing uses.

68. On information and belief, under 35 U.S.C. § 271(c), Breckenridge/Natco plans and intends to, and will, contribute to the infringement of the ’221 patent immediately and imminently upon approval of ANDA No. 208488.

69. The foregoing actions by Breckenridge/Natco constitute and/or would constitute infringement of the RE ’065 patent, active inducement of infringement of the ’221 patent and/or contribution to the infringement by others of the ’221 patent.

70. On information and belief, Breckenridge/Natco acted without a reasonable basis for believing that it would not be liable for infringing the ’221 patent, actively inducing infringement of the ’221 patent and/or contributing to the infringement by others of the ’221 patent.

71. There is a justiciable controversy between the parties hereto as to infringement of the '221 patent.

72. Plaintiffs will be substantially and irreparably damaged and harmed if Breckenridge/Natco’s infringement of the '221 patent is not enjoined.

73. Plaintiffs do not have an adequate remedy at law.

74. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT IV**
**Declaratory Judgment of Infringement of the ’221 Patent by Breckenridge/Natco**

75. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-74.

76. On information and belief, Breckenridge/Natco’s Proposed Generic Product contains the compound Erlotinib recited in one or more claims of the ’221 patent.

77. On information and belief, Breckenridge/Natco plans to begin manufacturing, marketing, selling, offering to sell and/or importing Breckenridge/Natco's Proposed Generic Product soon after FDA approval of ANDA No. 208488.

78. Such conduct will constitute direct infringement of one or more claims on the '221 patent under 35 U.S.C. § 271(a), inducement of infringement of the '221 patent under 35 U.S.C. § 271(b), and contributory infringement of the '221 patent under 35 U.S.C. § 271(c).

79. Breckenridge/Natco's infringing patent activity complained of herein is imminent and will begin following FDA approval of ANDA No. 208488.

80. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Breckenridge/Natco as to liability for the infringement of the '221 patent. Breckenridge/Natco's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Breckenridge/Natco's threatened imminent actions.

81. Plaintiffs will be irreparably harmed if Breckenridge/Natco is not enjoined from infringing the '221 patent.

82. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs OSI, Pfizer and Genentech respectfully request that the Court enter judgment against Breckenridge/Natco and for the following relief:

a. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Breckenridge/Natco infringed the RE '065 and '221 patents by submitting ANDA No. 208488 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell or import into the United States

Breckenridge/Natco's Proposed Generic Products prior to expiration of the RE '065 and '221 patents;

b. A judgment declaring that Breckenridge/Natco's manufacture, sale, offer for sale, marketing and distribution in, or importation into, the United States of the product described in Breckenridge's ANDA No. 208488 prior to expiration of the RE '065 and '221 patents will infringe, induce infringement and contribute to the infringement of at least one claim of the RE '065 and '221 patents;

c. A judgment pursuant to 35 U.S.C.§ 271(e)(4)(B) and/or 35 U.S.C. § 283 for a permanent injunction enjoining Breckenridge/Natco, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling Breckenridge/Natco's Proposed Generic Products within the United States, or importing Breckenridge/Natco's Proposed Generic Products into the United States, prior to the expiration of the RE '065 and '221 patents, and (ii) seeking, obtaining or maintaining approval of Breckenridge/Natco's Proposed Generic until expiration of the RE '065 and '221 patents or any later expiration of exclusivity to which Plaintiffs are or become entitled, or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 208488 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the RE '065 and '221 patents or any later expiration of exclusivity to which Plaintiffs are or become entitled;

e. If Breckenridge/Natco manufacture, use, offer to sell, or sell Breckenridge/Natco's Proposed Generic Products within the United States, or import Breckenridge/Natco's Proposed Generic Products into the United States, prior to the expiration

of the RE '065 and '221 patents, including any extensions, a judgment awarding Plaintiffs monetary relief including damages no less than a reasonable royalty and an accounting together with interest;

f. A declaration that this is an exceptional case action within the meaning of 35 U.S.C. § 285 and that Plaintiffs be awarded their attorneys' fees, costs and expenses incurred in prosecuting this action; and

g. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

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